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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,140	11/16/1999	BEKA SOLOMON	27/150	3910

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EXAMINER	
NICHOLS, CHRISTOPHER J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/441,140	SOLOMON, BEKA	
	Examiner	Art Unit	
	Christopher J Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 150-167* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-4* is/are allowed.

6)☒ Claim(s) *150-167* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 1999* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 23 February 2004 has been received and entered in full.

2. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is *withdrawn*.

3. The Preliminary Amendment filed 16 November 1999 has been received and entered in full.

4. The Amendment filed 8 January 2001 has been received and entered in full.

5. The Amendment filed 31 December 2001 has been received and entered in full.

6. The Amendment filed 21 June 2002 has been received and entered in full.

7. The Amendment filed 22 August 2002 has been received and entered in full.

8. Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,688,651 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

9. Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

10. These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

11. Should Applicant file any subsequent amendments to the specification and/or claims they must comply with 37 CFR 1.173(b).

12. In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed. Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will avoid rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

> "Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

14. The information disclosure statement filed 22 August 2002 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered because page 2 of the IDS is missing. Applicant is invited to provide a copy of page 2 and all the references therein at no additional cost.

Withdrawn Objections And/Or Rejections

15. The Objection to the Specification as set forth at pp. 3 ¶7-8 in the previous Office Action (22 August 2003) is *withdrawn* in view of Applicant's response and amendment (23 February 2004).

16. The rejection of claims **1-4** and **126-149** under 35 U.S.C. §251 as set forth at pp. 3 ¶9-11 in the previous Office Action (22 August 2003) is *withdrawn* in view of Applicant's filing of the original Letters Patent (US 5,688,651) pursuant to 37 C.F.R. §1.178 (23 February 2004).

17. All rejections of and objections to claims **126-149** as set forth in the previous Office Actions (22 August 2003) are *moot* in view of Applicant's cancellation of the claims (23 February 2004).

New Objections And/Or Rejections

18. Claim **164** is objected to because of the following informalities: the text of claim 164 is not legible. Applicant is invited to include a clear copy of claim 164 in the response to this Office Action. Appropriate correction is required.

19. Claims **150-167** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *a formulation comprising the antibody AMY33 or a fragment thereof and a carrier comprising same* (but only if it is available to the public—see subsequent lack of enablement due to deposit requirement), does not reasonably provide enablement for *any other antibodies with specificity to an epitope within residues 1-28 of beta-amyloid or pharmaceutical formulations*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to **make** or **use** the invention commensurate in scope with these claims.

20. The above inventions are drawn to pharmaceutical formulations comprising anti-β-amyloid antibody or an antigen binding fragments thereof, wherein said antibody and fragments

are effective to inhibit aggregation of β-amyloid or maintain β-amyloid solubility. The language of said claims encompasses both *in vivo* and *in vitro* use of the claimed invention.

21. The Specification provides examples of how monoclonal antibodies, CP_{10} and CP_9, specific for Carboxypeptidase A (CPA) inhibit temperature induced denaturing as measured by enzymatic activity (Figures 3 and 4). Figures 5 and 6 concern antibody binding to CPA, while it is not doubted that said antibodies (CP_{10} and CP_9) bind CPA. Figure 7 shows an Aβ aggregation assay performed with two anti-β-antibodies, 6F/3D.

22. While the specification prophetically considers antibodies other than the AMY33 antibody that may prevent or reduce aggregates or disaggregate aggregates in patients, the instant Specification does not provides sufficient guidance that would enable a skilled artisan to conceive of and make any other antibody that would inhibit aggregation or maintain solubility of β-amyloid in any given subject. Absent guidance and sufficient disclosure to adequately overcome obstacles of a therapeutic method, the endeavor to make the desired antibody is unpredictable and would require an undue amount of experimentation.

23. The claims, however, are drawn very broadly to antibodies and antigen binding fragments thereof capable of inhibiting β-amyloid aggregation or maintaining the solubility of β-amyloid. Since the specification fails to provide any guidance for the successful isolation or characterization of such a claimed antibody other than AMY33 capable of inhibiting β-amyloid aggregation or maintaining the solubility of β-amyloid in patients and since resolution of the various complications in β-amyloid aggregation makes the art highly unpredictable, one of skill in the art would have been unable to make the invention without engaging in undue trial and error experimentation.

24. In order to practice the invention using the specification and the state of the prior art as outlined above, the quantity of experimentation required to practice the invention as claimed *in vivo* would require the *de novo* determination of dosages, evaluation of effectiveness, and possibly new diagnosis methods as the only current method of examining β-amyloid plaques involves immunocytochemistry (see US 6399314 B1). While immunocytochemistry of mouse brains is readily practiced in the art, it is a hurdle that must be overcome to successfully practice the invention to its full scope in humans. In the absence of any guidance from the specification, the amount of experimentation would be undue, and one would have been unable to practice the invention over the scope claimed. The factors listed below have been considered in the analysis of enablement [see MPEP §2164.01(a) and *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)]:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

25. The following references are cited herein to illustrate the state of the art of β-amyloid.

26. On the state of the prior art, Walker *et al.* (July 1994) "Labeling of Cerebral Amyloid In Vivo with a Monoclonal Antibody." Journal of Neuropathology and Experimental Neurology **53**(4): 377-383 teaches the administration of a monoclonal anti-β-amyloid antibody (10D5) into the cerebrospinal fluid of aged monkeys (pp. 377). Following injection, the monkeys were sacrificed and their brains examined to confirm that the antibodies injected labeled Aβ plaques

(Figures 1-5). It is noted that the monoclonal anti-β-amyloid antibody (10D5) did not disaggregate or inhibit Aβ aggregation.

27. Concerning the breadth of the claims and the nature of the invention as a therapeutic, as noted above, no examples of diseases, disorders, injuries, or other maladies are provided by the instant Specification as filed or the prior art as to whether the antibodies claimed would be therapeutic. While putting forth the proposition of using the claimed antibodies as therapeutic agents, no evidence is present in the instant Specification or the prior art to guide the skilled artisan to use AMY33 as a therapeutic. What remains is an invitation to experiment, first to determine whether AMY33 has any effect, then determine its mode of action, and finally the course of therapy that would have a salubrious outcome [see MPEP §2164.01(a)]. Thus in the absence of guidance and working examples, the skilled artisan is confronted with an undue burden of experimentation in an unpredictable and undeveloped art to practice the invention as claimed.

28. Moreover on the nature of the invention, of the two anti-β-amyloid antibodies disclosed in the instant Specification, Akiyama *et al.* (15 February 1999) "Occurrence of the diffuse amyloid beta-protein (Abeta) deposits with numerous Abeta-containing glial cells in the cerebral cortex of patients with Alzheimer's disease." Glia **25**(4): 324-331 teaches that 6F/3D does not readily bind Aβ plaques in cerebral cortex samples from an Alzheimer's patient. Thus the skilled artisan is presented with evidence contrary to the claim that 6F/3D will bind naturally occurring aggregates, the first step in "disaggregation".

29. The specification as filed does not provide any guidance or examples that would enable a skilled artisan to make the claimed antibodies. Additionally, a person skilled in the art would

recognize that predicting the efficacy of making an antibody *in vivo* based solely on its prophetic considerations and desired properties as highly problematic. Thus, although the specification prophetically considers and discloses general methodologies of making the claimed antibody for *in vivo* therapeutic regiments, such a disclosure would not be considered enabling since the state of β-amyloid aggregation and anti-β-amyloid antibodies is highly unpredictable.

30. Claims **150-167** are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

31. The invention employs a novel monoclonal antibody, AMY33. Since the AMY33 monoclonal antibody is essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. The specification does not disclose a repeatable process to obtain the AMY33 monoclonal antibody and it is not apparent if the AMY33 monoclonal antibody is readily available to the public. If the AMY33 monoclonal antibody is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the AMY33 monoclonal antibody.

32. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific antibody molecules have been deposited under the Budapest Treaty and that the AMY33 monoclonal antibody will be irrevocably and without restriction or

condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

33. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

34. Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include such, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other

information. Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

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10801 University Boulevard

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35. Claims **150-167** are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

36. The independent claims require "an antibody or antigen binding fragment thereof' that inhibits aggregation of or maintains the solubility of soluble β-amyloid but do not require that the antibody or fragment thereof to possess any particular conserved structure, or other distinguishing feature. Thus, the claims are drawn to a genus of agents that is defined by novelty.

37. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claim that is sufficiently disclosed is the AMY33 antibody and antigen binding fragments thereof. The specification does not identify any particular portion of the structure that must be

conserved, nor does it provide a disclosure of structure/function correlation. The distinguishing characteristics of the claimed genus are not described. Accordingly, the specification does not provide adequate written description of the claimed genus.

38. To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572.

39. See *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003) and *University of Rochester v. G.D. Searle & Co. et al.* CAFC [(03-1304) 13 February 2004]. In *University of Rochester v. G.D. Searle & Co.* a patent directed to method for inhibiting prostaglandin synthesis in human host using an unspecified compound, in order to relieve pain without side effect of stomach irritation, did not satisfy written description requirement of 35 U.S.C. §112, since the patent described the compound's desired function of reducing activity of the enzyme PGHS-2 without adversely affecting PGHS-1 enzyme activity, but did not identify

said compound, since invention consists of performing "assays" to screen compounds in order to discover those with desired effect. The patent did not name even one compound that assays would identify as suitable for practice of the invention, or provide information such that one skilled in art could identify a suitable compound. And since the specification did not indicate that compounds are available in public depository, the claimed treatment method cannot be practiced without the compound. Thus the inventors cannot be said to have "possessed" the claimed invention without knowing of a compound or method certain to produce said compound. Thus said patent constituted an invitation to experiment to first identify, then characterize, and then use a therapeutic class of compounds defined only by their desired properties.

40. Withal, in *Randolph J. Noelle v Seth Lederman, Leonard Chess and Michael J. Yellin* (CAFC, 02-1187, 20 January 2004) the CAFC held that "Therefore, based on our past precedent, as long as an applicant has disclosed a "fully characterized antigen," either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen.

41. Noelle did not provide sufficient support for the claims to the human CD40CR antibody in his '480 application because Noelle failed to disclose the structural elements of human CD40CR antibody or antigen in his earlier '799 application. Noelle argues that because antibodies are defined by their binding affinity to antigens, not their physical structure, he sufficiently described human CD40CR antibody by stating that it binds to human CD40CR antigen. Noelle cites Enzo Biochem II for this proposition. This argument fails, however, because Noelle did not sufficiently describe the human CD40CR antigen at the time of the filing

of the '799 patent application. In fact, Noelle only described the mouse antigen when he claimed the mouse, human, and genus forms of CD40CR antibodies by citing to the ATCC number of the hybridoma secreting the mouse CD40CR antibody. If Noelle had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by simply stating its binding affinity for the "fully characterized" antigen. Noelle did not describe human CD40CR antigen. Therefore, Noelle attempted to define an unknown by its binding affinity to another unknown. As a result, Noelle's claims to human forms of CD40CR antibody found in his '480 application cannot gain the benefit of the earlier filing date of his '799 patent application.

42. Moreover, Noelle cannot claim the genus form of CD40CR antibody by simply describing mouse CD40CR antigen."

43. Therefore the full breadth of the claim fails to meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

44. Claims **150, 151, 156, 157, 162,** and **163** are rejected under 35 U.S.C. 102(a) as being anticipated by Bickel *et al.* (March/April 1994) "Development and in Vitro Characterization of a

Cationized Monoclonal Antibody against βA4 Protein: A Potential Probe for Alzheimer's Disease." Bioconjugate **5**(2): 119-125.

45. Bickel *et al.* teaches the AMY33 antibody which recognizes an epitope within residues 1-28 of β-amyloid thus meeting the limitations of claims 150, 156, and 162 (pp. 120; Figures 3 & 4). The AMY33 antibody is a monoclonal antibody thus meeting the limitations of claims 150, 156, and 162 (pp. 120).

46. Bickel *et al.* teaches a solution of the AMY33 antibody in TBS (50 mM Tris, pH=7.4, 0.9% NaCl) thus meeting the limitations of claims 150, 156, and 162 (pp. 121). The recitation in the claims "pharmaceutical formulation" is interpreted as an intended use and is not given patentable weight in this art rejection. Also, use of the composition of Bickel *et al.* is not inconsistent with such treatment.

47. The claims recite functional properties assigned to the claimed antibody including "inhibits β-amyloid aggregation" and/or "maintains soluble β-amyloid solubility", but the AMY33 antibody as taught by Bickel *et al.* is the same antibody as instantly claimed. Since a compound and all of its properties are inseparable, although Bickel *et al.* is silent on said properties they are taken to be the same antibodies (***In re Papesch***, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)).

48. Claims **150, 151, 156, 157, 162,** and **163** are rejected under 35 U.S.C. 102(b) as being anticipated by Stern *et al.* (May 1989) "Monoclonal antibodies to a synthetic peptide homologous with the first 28 amino acids of Alzheimer's disease beta-protein recognize amyloid

and diverse glial and neuronal cell types in the central nervous system." Am J Pathol. 1989 **134**(5): 973-978.

49. Stern *et al.* teaches the AMY33 antibody which recognizes an epitope within residues 1-28 of β-amyloid thus meeting the limitations of claims 150, 156, and 162 (pp. 977). The AMY33 antibody is a monoclonal antibody thus meeting the limitations of claims 150, 156, and 162 (pp. Table I).

50. Stern *et al.* teaches a solution of the AMY33 antibody in ELISA solution thus meeting the limitations of claims 150, 156, and 162 (pp. 974). The recitation in the claims "pharmaceutical formulation" is interpreted as an intended use and is not given patentable weight in this art rejection. Also, use of the composition of Stern *et al.* is not inconsistent with such treatment.

51. The claims recite functional properties assigned to the claimed antibody including "inhibits β-amyloid aggregation" and/or "maintains soluble β-amyloid solubility", but the AMY33 antibody as taught by Stern *et al.* is the same antibody as instantly claimed. Since a compound and all of its properties are inseparable, although Stern *et al.* is silent on said properties they are taken to be the same antibodies (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)).

Summary

52. Claims **1-4** are free of the art.

53. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
June 8, 2004

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600